

ing, or other symptoms of appendicitis were present; and the labeling failed to warn against unsafe methods or duration of administration since it failed to warn that frequent or continued use of the article might result in dependence on laxatives.

On May 15, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

713. Misbranding of Special Formula Tablets S. C. Purple. U. S. v. 51,000 Special Formula Tablets S. C. Purple. Default decree of condemnation and destruction. (F. D. C. No. 6902. Sample No. 40889-E.)

These tablets contained strychnine and the labeling failed to bear adequate directions for use and such adequate warnings as are necessary for the protection of users.

On February 20, 1942, the United States attorney for the Eastern District of Pennsylvania filed a libel against the above-named product at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about October 20, 1941, by the Purity Drug Co. from Passaic, N. J.; and charging that it was misbranded.

Analysis showed that the article contained yohimbé bark, a strychnine compound, a magnesium compound, zinc phosphide, and extracts of plant drugs, such as damiana.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use since the statement on the drum label, "Dose: To be taken as directed by physician," did not constitute adequate directions for use. It was alleged to be misbranded further in that its labeling failed to bear such adequate warnings against use by children where its use might be dangerous to health, or against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users since there were no warnings against frequent or long continued use under circumstances which might result in strychnine poisoning, nor was there any warning that the use of the article, because of its strychnine content, might be particularly dangerous to children and aged persons.

On May 1, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

714. Misbranding of Spicer's Compound. U. S. v. 117 Bottles of Spicer's Compound. Default decree of condemnation and destruction. (F. D. C. No. 6966. Sample No. 71519-E.)

This product was a laxative and its labeling failed to bear the required laxative warnings, failed to declare the strychnine and belladonna alkaloids present, failed to name the principal physiologically active ingredient under its common or usual name, and also bore false and misleading curative and therapeutic claims.

On March 2, 1942, the United States attorney for the Eastern District of Missouri filed a libel against 117 bottles of Spicer's Compound at St. Louis, Mo., alleging that the article had been shipped in interstate commerce on or about October 22, 1941, and January 21, 1942, by the Charles R. Spicer Co. from Memphis, Tenn.; and charging that it was misbranded.

Analysis showed that the article consisted essentially of a solution of Epsom salt (approximately 25 percent) with relatively small proportions of extracts of plant drugs including laxative plant drugs, and a small proportion of an iron salt, sweetened with saccharin and preserved with sodium benzoate.

The article was alleged to be misbranded (1) in that its labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health and against unsafe duration of administration in such manner and form as are necessary for the protection of users, since the statement on the label, "Caution—In case of severe abdominal pain, do not take a laxative" was not adequate to warn the purchaser against the use of the article in case of abdominal pain, nausea, vomiting, or other symptoms of appendicitis and did not warn the purchaser that frequent or continual use of the article might result in dependence upon laxatives to move the bowels; (2) in that the following statements in the labeling "Spicer's Compound * * * to aid in the relief of simple headache, heartburn, biliousness, sour stomach, gas in stomach and intestines due to occasional constipation" were misleading since they failed to reveal the material fact that the conditions mentioned are usually due to causes other than occasional constipation and that the article was not a treatment for such conditions when due to such other causes; (3) in that the statements, "Contains: Nux-Vomica 1.8 min. to ounce. Belladonna .45 min. to

ounce Herbs—including Senna, Buchu, Juniper Berries, Rhubarb, Jalap; Magnesium Sulphate, Cascara, & Iron (Ferric Chloride)," were misleading since they failed to reveal the fact that the physiological effects of the article were due essentially to its content of Epsom salt (magnesium sulfate), senna, and cascara sagrada; (4) in that the label failed to bear the common or usual name of each active ingredient, since magnesium sulfate is not the common or usual name of Epsom salt; and (5) in that its label failed to bear the name and quantities or proportions of strychnine, atropine, hyoscine, and hyoscyamine that were present.

On March 28, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

715. Misbranding of Starr's Wonderful M. L. & K. Pills. U. S. v. Fred Marlon Starr (Starr Medicine Co.). Plea of nolo contendere. Fine, \$100. (F. D. C. No. 6415. Sample No. 30265-E.)

The labeling of this product, in addition to failure to bear adequate warning statements, contained false and misleading claims and failed to bear the required ingredient and accurate quantity of contents statements.

On March 24, 1942, the United States attorney for the Northern District of California filed an information against Fred Marlon Starr, trading as the Starr Medicine Co. at San Francisco, Calif., alleging shipment on or about February 18, 1941, from the State of California into the State of Illinois of a quantity of the above-named product that was misbranded.

Analysis of a sample of the article showed that it consisted essentially of extracts of plant drugs, including a laxative drug, coated with calcium carbonate.

It was alleged to be misbranded: (1) In that its labeling failed to bear adequate warnings against use in those pathological conditions where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form as are necessary for the protection of users, since it was a cathartic or laxative drug, and the labeling failed to bear a warning that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent or continued use might result in dependence on laxatives. (2) In that statements on the label, representing that it would be efficacious in the treatment of weak back, liver and kidney complaints, biliousness, fever, headaches, and indigestion were false and misleading since it would not be efficacious for such purposes. (3) In that it was fabricated from two or more ingredients and its label did not bear a statement of the common or usual name of each active ingredient. (4) In that it was in package form and did not bear a label containing an accurate statement of the quantity of contents in terms of numerical count.

On April 6, 1942, the defendant entered a plea of nolo contendere and the court imposed a fine of \$100.

716. Misbranding of Weltone. U. S. v. 4 Cartons of Weltone and Accompanying Circulars. Default decree of condemnation and destruction. (F. D. C. No. 6792. Sample No. 70631-E.)

The labeling of this product failed to bear adequate directions for use and also bore false and misleading curative and therapeutic claims.

On January 31, 1942, the United States attorney for the Middle District of North Carolina filed a libel against 4 cartons (144 bottles) of Weltone and accompanying circulars, alleging that the article had been shipped in interstate commerce on or about January 10, 1942, by Standard Chemical, Inc., from Brooklyn, N. Y.; and charging that it was misbranded.

Analysis showed that the article consisted of a water solution of Epsom salt (28 percent) with inconsequential amounts of other salts, flavored with cassia and clove oils and sweetened with saccharin.

The article was alleged to be misbranded in that its labeling failed to bear adequate directions for use, since the following directions "Adults, about one to two tablespoonfuls twice daily in water before meals. Children (7 years or older): One teaspoonful in water before meals," provided for continued use, which might result in dependence upon laxatives. (2) In that the syllable "tone" forming a part of its name and the statements in an accompanying circular which represented that it would increase the appetite, prevent or cure headaches or run-down feeling, establish regularity in elimination, correct sluggish digestion, remedy incomplete elimination or sour stomach, prevent weakening run-down feeling due to constipation; that a periodic dose would